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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,531	11/10/2003	Kun Ping Lu	2312/2002	8129

7590 07/07/2006

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,531	LU ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *2,7-46,48,49 and 52-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,47,50 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/18/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1, 3-6, 47, 50 and 51 in the reply filed on May 22, 2006 is acknowledged. The traversal is on the ground(s) that it is unclear as to what was meant by the statement in the restriction requirement that claims 3-6 and 14-69 were presented in an improper Markush format since claims 3-6 are drawn to nucleic acids and not to methods. To clarify, the reference to the fact that the claims encompassed methods which analyzed distinct targets was made to respect to claims 14-69. However, the restriction requirement as it applies to claims 3-6 is also maintained because these claims recite an improper Markush group since the members of the recited Markush group do not share a common structure and function (see MPEP 803.02). Specifically, claims 3-6, 47, 50 and 51 are drawn to vectors, host cells and nucleic acids comprising the PinX1 polynucleotides of SEQ ID NO: 1 or 2 or the PinX1-LI polynucleotides of SEQ ID NO: 5. The PinX1 polynucleotides of SEQ ID NO: 1 and 2 consist of a different nucleotide sequence, have different hybridization properties and encode for proteins having a different functional activities compared to the PinX1-LI polynucleotides of SEQ ID NO: 5. Accordingly, it is maintained that claims 3-6 do not recite a proper Markush group (i.e., the group of polynucleotides comprising SEQ ID NO: 1 or 2 being distinct from the group of polynucleotides comprising SEQ ID NO: 5) and restriction of the subject matter of these claims is proper.

The requirement is still deemed proper and is therefore made FINAL.

Thereby, claims 1, 3-6, 47, 50 and 51 have been examined herein. Claims 2, 7-46, 48, 49, and 52-69 are withdrawn from consideration as being drawn to a non-elected invention.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See, for example, page 62. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50 and 51 are indefinite over the recitation of "complementary." The specification (page 22) defines complementary nucleic acids as sequences that "hybridize specifically to another polynucleotide sequence." However, this definition is vague since the definition does not set forth what the polynucleotide sequence hybridizes to. Further, the phrase "specific hybridization" is vaguely defined in the specification as referring to the formation of hybrids between a probe and a specific target. It is stated that specific hybridization occurs when, for example, a probe "preferentially hybridizes to a specific target so that a single band is observed on Southern blot." This disclosure is not considered to provide a complete and fixed

definition for the phrase "specific hybridization" since the disclosure provides only an example of what might be encompassed by this phrase. Also, the definition does not clearly set forth what constitutes preferential hybridization. The skilled artisan cannot determine the meets and bounds of the claimed invention because the claims do not set forth the conditions for determining whether the polynucleotide has or has not hybridized. It is unclear as to whether such nucleic acids hybridize only to SEQ ID NO: 1 (and thereby are fully complementary to SEQ ID NO: 1) or if such nucleic acids also hybridize with variants of SEQ ID NO: 1 (e.g., variants having 99%, 98%, 95%, 90%, 70% etc identity with SEQ ID NO: 1). In the later case, there are no specific teachings provided in the specification to indicate the cut-off point at which the nucleic acid no longer specifically hybridizes to SEQ ID NO: 1. If the claimed nucleic acid is capable of hybridizing with a nucleic acid that differs from SEQ ID NO: 1 by even 1 nucleotide, then such nucleic acids are not truly specific for SEQ ID NO: 1. Additionally, claims 50 and 51 are indefinite over the recitation of "corresponding." This term is defined in the specification at page 22 as referring to nucleic acid sequences that are "complementary to all or a fragment comprising 10 or more consecutive nucleotides of a reference polynucleotide or encoding an amino acid sequence at least 70%...identical to an amino acid sequence in a peptide or protein." Since "corresponding" sequences are defined in terms of being complementary, and the term "complementary" is indefinite for the reasons stated above, the phrase "corresponding mRNA sequences" is also indefinite. Corresponding is not an art recognized term to describe the relationship between two nucleic acid sequences. It is not clear as to whether a corresponding mRNA refers to a mRNA encoded by the cDNA of SEQ ID NO: 1 or if this refers to sequences similar to SEQ ID NO: 1 or sequences which map to the same region as SEQ ID NO: 1 or homologues of SEQ ID NO: 1, etc. Because the term "corresponding" has not been

clearly defined in the specification and because there is no art recognized definition for this term as it relates to nucleic acid sequences, one of skill in the art cannot determine the meets and bounds of the claimed subject matter.

4. Claims 1, 3-6, 47, 50 and 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1 and 3-6 are drawn to polynucleotides "comprising a sequence of SEQ ID NO: 1 or 2." In view of the "comprising **a sequence**" language, the claims have been interpreted as encompassing polynucleotides comprising any portion of SEQ ID NO: 1 or 2 (i.e., 1, 2, 3 nucleotides etc of SEQ ID NO: 1 or 2). The claims do not define the complete polynucleotide in terms of the sequences which flank the portion of SEQ ID NO: 1 or 2 or in terms of the biological activity of the polynucleotide. Additionally, claims 1, 3-6 and 47 encompass polynucleotides comprising SEQ ID NO: 2. SEQ ID NO: represents a portion of the cDNA encoding the terminal 74 amino acids of the PINX1 protein (SEQ ID NO: 3). Claims 1, 3-6 and 47 also do not define the 5' nucleotides flanking SEQ ID NO: 2 or the overall functional activity of the claimed polynucleotide. Claims 50 and 51 are drawn to antisense polynucleotides complementary to the corresponding mRNA sequence comprising SEQ ID NO: 1. As discussed in paragraph 3 above, the terms "complementary" and "corresponding" have not been clearly defined in the specification. As such, these terms have been given their broadest reasonable

interpretation and have been interpreted as including polynucleotides which share any level of sequence complementarity (10%, 20%...70%...80% etc) to SEQ ID NO: 1 or a sequence that shares any level of sequence identity with SEQ ID NO: 1 or a fragment thereof. Accordingly, the claims encompass a very large genus of splice variants, allelic variants, non-naturally occurring variants and homologues of SEQ ID NO: 1. Additionally, the claims include polynucleotides having any functional activity since the claims do not recite any particular biological activity for the nucleic acid or the encoded polypeptide.

While nucleic acids comprising SEQ ID NO: 1 and nucleic acids consisting of SEQ ID NO: 2 meet the written description requirements, the specification does not provide an adequate written description of the claimed genus of nucleic acids comprising a portion of SEQ ID NO: 1 or 2 or comprising a sequence sharing any level of sequence complementary with SEQ ID NO: 1 or 2 or a portion thereof.

The specification teaches the full length cDNA sequence of SEQ ID NO: 1, which encodes for PINX1. The specification teaches that PINX1 binds to Pin2/TFR1 (page 65) and binds to and inhibits telomerase (page 70). The specification also teaches a fragment of SEQ ID NO: 1 (i.e., SEQ ID NO: 2) which encodes for a peptide which binds to and inhibits telomerase (referred to therein as "TID" – telomerase inhibitory domain). Additionally, a polynucleotide referred to as "PinX1-L1" and comprising SEQ ID NO: 5 is also disclosed. However, the specification does not disclose the functional activity of this polynucleotide or its specific relationship to PinX1.

The specification does not specifically disclose any specific naturally or non-naturally occurring mutants, allelic variants, splice variants or homologues of SEQ ID NO: 1.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, 1 member of the genus of PINX1 polynucleotides has been identified. No additional nucleotide variations have been

disclosed. It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. restriction map, biological activity of an encoded protein product, etc.). In the instant case, no such identifying characteristics have been provided for any of allelic variants, splice variants, or mutant PinX1 polynucleotides. However, the claims as written are inclusive of a potentially large genus of mutations in the PinX1 gene. While one could contemplate a nucleotide substitution, deletion or addition at each and every position in the PinX1 gene, such nucleotide variations are not considered to be equivalent to specific nucleotide variations associated with telomerase inhibition. Rather, mutations in the PinX1 associated with telomerase inhibition represent a distinct group of nucleotide variations which are expected to occur at only specific locations within the gene and consist of specific nucleotide alterations. Accordingly, knowledge of the sequence of the wild-type gene does not allow the skilled artisan to envision all of the contemplated polymorphisms encompassed by the claimed genus. Conception of the claimed invention cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of potential methods for isolating additional nucleotide variations. As stated in *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. LTD*, 25 USPQ2d 1016, one cannot describe what one has not conceived.

The general knowledge in the art concerning homologues, mutants, allelic and splice variants does not provide any indication of how modification of the sequence of SEQ ID NO: 1 will effect the functional properties of SEQ ID NO: 1. The structure and

function of one molecule does not provide guidance as to the structure and function of other molecules. Therefore, the description of one molecule (SEQ ID NO: 1) is not representative of a genus of homologues, splice, mutant and allelic variants of SEQ ID NO: 1 having unspecified functional activities different from that of SEQ ID NO: 1. A general statement in the specification of a desire to obtain gene sequences, homologues from other species, mutated species, SNPs, polymorphic sequences, promoter sequences and exogenous sequences is not equivalent to providing a clear and complete description of specific sequences which fall within the claimed genus of nucleic acids.

Accordingly, the disclosure in the specification of 1 PinX1 polynucleotide is not considered to constitute a representative number of the splice variants, allelic variants, mutants and homologues of PinX1 encompassed by the claims. For these reasons, Applicants have not provided sufficient evidence that they were in possession, at the time of filing, of the invention as it is broadly claimed and thus the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

4. Claims 1, 3-6, 47, 50 and 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polynucleotides comprising SEQ ID NO: 1 and isolated polynucleotides consisting of SEQ ID NO: 2, does not reasonably provide enablement for polynucleotides comprising SEQ ID NO: 2 or

comprising "a sequence" (i.e., a fragment) of SEQ ID NO: 1 or 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands,* 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

Breadth of the Claims:

Claims 1 and 3-6 are drawn to polynucleotides "comprising a sequence of SEQ ID NO: 1 or 2." In view of the "comprising **a sequence**" language, the claims have been interpreted as encompassing polynucleotides comprising any portion of SEQ ID NO: 1 or 2 (i.e., 1, 2, 3 nucleotides etc of SEQ ID NO: 1 or 2). The claims do not define the complete polynucleotide in terms of the sequences which flank the portion of SEQ ID NO: 1 or 2 or in terms of the biological activity of the polynucleotide. Additionally, claims 1, 3-6 and 47 encompass polynucleotides comprising SEQ ID NO: 2. SEQ ID NO: represents a portion of the cDNA encoding the terminal 74 amino acids of the PINX1 protein (SEQ ID NO: 3). Claims 1, 3-6 and 47 also do not define the 5' nucleotides flanking SEQ ID NO: 2 or the overall functional activity of the claimed polynucleotide. Claims 50 and 51 are drawn to antisense polynucleotides complementary to the

corresponding mRNA sequence comprising SEQ ID NO: 1. As discussed in paragraph 3 above, the terms "complementary" and "corresponding" have not been clearly defined in the specification. As such, these terms have been given their broadest reasonable interpretation and have been interpreted as including polynucleotides which share any level of sequence complementarity (10%, 20%...70%...80% etc) to SEQ ID NO: 1 or a sequence that shares any level of sequence identity with SEQ ID NO: 1 or a fragment thereof. Accordingly, the claims encompass a very large genus of splice variants, allelic variants, non-naturally occurring variants and homologues of SEQ ID NO: 1. Additionally, the claims include polynucleotides having any functional activity since the claims do not recite any particular biological activity for the nucleic acid or the encoded polypeptide.

Nature of the Invention:

The claims are drawn to polynucleotides comprising SEQ ID NO: 1 or 2 or fragments thereof. The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F. 3d 1316, 1330 (Fed Cir. 2001).

State of the Art:

The specification teaches the full length cDNA sequence of SEQ ID NO: 1, which encodes for PINX1. The specification teaches that PINX1 binds to Pin2/TFR1 (page 65) and binds to and inhibits telomerase (page 70). The specification also teaches a fragment of SEQ ID NO: 1 (i.e., SEQ ID NO: 2) which encodes for a peptide which binds to and inhibits telomerase (referred to therein as "TID" – telomerase inhibitory domain).

Additionally, a polynucleotide referred to as "PinX1-L1" and comprising SEQ ID NO: 5 is also disclosed. The PinX1-L1 amino acid sequence shares 73% identity with the amino acid sequence encoded by SEQ ID NO :1 (see Figure 12). However, the specification does not disclose the functional activity of this polynucleotide or its specific relationship to PinX1.

The Predictability or Unpredictability of the Art and Degree of Experimentation:

The prior art acknowledges the unpredictability in modifying the nucleotide sequence of a gene. Modification of even a single nucleotide within a coding or non-coding sequence can significantly alter the functional properties of that gene and protein encoded thereby. While the specification teaches that the C-terminal domain of the PinX1 polypeptide is important for telomerase binding activity, the specification does not teach any particular amino acids therein which are critical for maintaining binding activity and does not teach any particular nucleotides within the full length PinX1 polynucleotide which encode for amino acids that are critical for other functional activities and/or for maintaining the three dimensional structure of the encoded protein. Thereby, it is highly unpredictable as to how modifying sequences within SEQ ID NO: 1 will effect the overall functional properties of the resulting gene and polypeptide encoded thereby. It is also unpredictable as to how adding nucleotides of any identity or length to the terminus of SEQ ID NO: 2 or to fragments of 1, 2, 3 etc nucleotides of SEQ ID NO: 1 or 2 will effect the functional properties of the resulting nucleic acid and encoded polypeptide.

Amount of Direction or Guidance Provided by the Specification:

The specification does not provide any specific guidance as to how to predictably make and use nucleic acids comprising any portion of SEQ ID NO: 1 or 2 flanked by nucleotides of any length and identity. While one could generate a significantly large genus of nucleic acids in which nucleotides of any identity are added to the 5' or 3' terminus of SEQ ID NO: 2 or fragments of SEQ ID NO: 1 or 2 or in which any number of nucleotides within SEQ ID NO: 1 or 2 are mutated via substitution, addition or deletion, and then assay each of these nucleic acids to try to determine their biological activity, such trial-by-error experimentation is considered to be undue. Providing methods for searching for additional nucleic acids and trying to determine the function of the resulting nucleic acid or trying to establish an association between the nucleic acids and asthma is not equivalent to teaching how to make and use specific nucleic acids.

Working Examples:

Again, the specification teaches only a full length cDNA comprising SEQ ID NO: 1 and one fragment thereof – i.e. a polynucleotide consisting of SEQ ID NO: 2, wherein said polynucleotide encodes for a polypeptide which binds Pin2/TRF-1 and telomerase . The specification does not provide any working examples of how to predictably make and use nucleic acids comprising SEQ ID NO: 2 or comprising fragments of SEQ ID NO: 1 or 2. There is no disclosure in the specification of additional nucleic acids which contain any number or identity of nucleotides flanking the recited polymorphisms, other than nucleic acids which contain the sequences of SEQ ID NO: 1 or which consist of the sequence of SEQ ID NO: 2. In particular, there are no specific working examples

provided in the specification of splice variants, mutants or allelic variants of PinX1 which have a specific and useful functional activity.

Conclusions:

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art. Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant case, the claims do not bear a reasonable correlation to the scope of enablement because the specification teaches only 1 members of the broadly claimed genus of nucleic acids, namely SEQ ID NO: 3, whereas the claims encompass a significantly large genus of nucleic acids, in which the overall structural and functional properties of the nucleic acids are not defined. As set forth above, in view of the unpredictability in the art, extensive experimentation would be required to make and use the broadly claimed genus of homologues, mutant, allelic and splice variants of SEQ ID NO: 1 because the specification does not provide sufficient guidance as to how to select the nucleotides which may flank fragments of SEQ ID NO:

1 or 2 or how to select nucleotides within SEQ ID NO: 1 or 2 that may be modified by insertion, deletion or substitution and does not teach a predictable means for determining the functional properties of such nucleic acids. Accordingly, although the level of skill in the art of molecular biology is high, given the lack of disclosure in the specification and in the prior art, it would require undue experimentation for one of skill in the art to make and use the broadly claimed invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6, 50 and 51 are rejected under 35 U.S.C. 102(a) as being anticipated by Liao et al (Hepatology. Oct 2000. 32: 721-727; cited in the IDS).

The claims are drawn to an isolated PinX1 polynucleotide comprising a sequence of SEQ ID NO: 1 or 2. In view of the recitation in the claims of "a sequence," the claims have been interpreted as including a polynucleotide comprising a portion of SEQ ID NO: 1 or 2.

Liao et al (Figure 1; deposited as GenBank Accession NO: AF205718 – see page 721) teach a LPTS polynucleotide that encodes the first 132 amino acid residues encoded by SEQ ID NO: 1. The nucleic acid of Liao shares 59% identity and 93% best local similarity with nucleotides 19-1302 of SEQ ID NO: 1 (see below). Accordingly, Liao

teaches a polynucleotide comprising a portion of SEQ ID NO: 1 and 2 and thereby anticipates the claimed invention. With respect to claims 3 and 4, Liao et al (page 722) further teaches vectors and host cells comprising said polynucleotide. With respect to claims 5 and 6, Liao et al (page 722) teaches a radioactively labeled 800 nucleotide fragment of the LPTS polynucleotide. With reference to claims 50 and 51, the polynucleotide solutions taught by Liao et al are considered to be pharmaceutical compositions because these solutions could be used for pharmaceutical purposes.

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Query Match 59.0%; Score 1107.2; DB 5; Length 1316;
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Matches 1199; Conservative 0; Mismatches 8; Indels 77; Gaps 1;
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Db 711
CCACAGGTAAAGATGTGGAAAGTTACCTCCAGCCTAAGGCCAAGAGGCACACGGAGGGAA
770
Qy 799
AGCCCGAGAGGGCCGAGGCCCAGGAGCGAGTGGCCAAGAAGAAGTGCGCGCCAGCAGAAA
858
|||||||||||||||||||||||||||||||||||||||| ||||||||||||||
Db 771
AGCCCGAGAGGGCCGAGGCCCAGGAGCGAGTGGCCAAGAAGAAGAGCGCGCCAGCAGAAG
830
Qy 859
AACAGCTCAGAGGCCCCTGCTGGGACCAGAGTTCCAAGGCCTCTGCTCAGGATGCAGGGG
918
| ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 831
AGCAGCTCAGAGGCCCCTGCTGGGACCAGAGTTCCAAGGCCTCTGCTCAGGATGCAGGGG
890
Qy 919
ACCATGTGCAGCCGCCTGAGGGCCGGGACTTCACCCTGAAGCCCAAAAAGAGGAGAGGGA
978
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 891
ACCATGTGCAGCCGCCTGAGGGCCGGGACTTCACCCTGAAGCCCAAAAAGAGGAGAGGGA
950
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Qy 979
AGAAAAAGCTGCAAAAACCAGTAGAGATAGCAGAGGACGCTACACTAGAAGAAACGCTAG
1038
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 951
AGAAAAAGCTGCAAAAACCAGTAGAGATAGCAGAGGACGCTACACTAGAAGAAACGCTAG
1010
Qy 1039
TGAAAAAGAAGAAGAAGAAAGATTCCAAATGAATCCTTCCCAGCCGGGGCCTTCCGACCA
1098
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 1011
TGAAAAAGAAGAAGAAGAAAGATTCCAAATGAATCCTTCCCAGCCGGGGCCTTCCGACCA
1070
Qy 1099
CTCAGCTGTCAGGGCACTGCGGGGGCAGACACCTCTGGCCTGAAGTCACAGCAGAGTTCA
1158
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 1071
CTCAGCTGTCAGGGCACTGCGGGGGCAGACACCTCTGGCCTGAAGTCACAGCAGAGTTCA
1130
Qy 1159
CCCCAGAGCGCCTGGGCGCATCTTGTGGCATGCCCATGGGCTGCCGAGTCCTGCCCTCTC
1218
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 1131
CCCCAGAGCGCCTGGGCGCATCTTGTGGCATGCCCATGGGCTGCCGAGTCCTGCCCTCTC
1190
Qy 1219
GCCACATTTCCCCCAAGTTACATTCCCAGGAGGACCTTTTTAATGTTCTCAATCGTGGCT
1278
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 1191
GCCACATTTCCCCCAAGTTACATTCCCAGGAGGACCTTTTTAATGTTCTCAATCGTGGCT
1250
Qy 1279 CTCAGACACAAATAAATTCTCGTG 1302
||||||||||||||||||  |  ||
Db 1251 CTCAGACACAAATAAATTTTTTTG 1274
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6. Claims 1, 3-4, 50 and 51 are rejected under 35 U.S.C. 102(a) as being anticipated by Liao et al (GenBank Accession No. AF205718).

The claims are drawn to an isolated PinX1 polynucleotide comprising a sequence of SEQ ID NO: 1 or 2. In view of the recitation in the claims of "a sequence," the claims have been interpreted as including a polynucleotide comprising a portion of SEQ ID NO: 1 or 2.

Liao teaches a polynucleotide that encodes the first 132 amino acid residues encoded by SEQ ID NO: 1. The nucleic acid of Liao shares 59% identity and 93% best local similarity with nucleotides 19-1302 of SEQ ID NO: 1 (see alignment in paragraph 5 above). Accordingly, Liao teaches a polynucleotide comprising a portion of SEQ ID NO: 1 and 2 and thereby anticipates the claimed invention. With respect to claims 3 and 4, Liao et al further teaches vectors and host cells comprising said polynucleotide. With reference to claims 50 and 51, the polynucleotide solutions taught by Liao et al are considered to be pharmaceutical compositions because these solutions could be used for pharmaceutical purposes.

7. Claims 1, 3-6, 50 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillman et al (WO 99/57270).

The claims are drawn to an isolated PinX1 polynucleotide comprising a sequence of SEQ ID NO: 1 or 2. In view of the recitation in the claims of "a sequence," the claims have been interpreted as including a polynucleotide comprising a portion of SEQ ID NO: 1 or 2.

Hillman et al teaches a polynucleotide that shares 99% identity with nucleotides 19 to 1302 of SEQ ID NO: 1. Hillman also teaches a polynucleotide that comprises fragments which are 100% identical to fragments of SEQ ID NO: 1 and 2 (e.g.,

nucleotides 136-464 of Hillman are 100% identical to nucleotides 19-346 of SEQ ID NO: 1; see alignment below). Accordingly, Hillman teaches a polynucleotide comprising a portion of SEQ ID NO: 1 or SEQ ID NO: 2 and thereby anticipates the claimed invention. With respect to claims 3 and 4, Hillman et al (page 7) further teaches vectors and host cells comprising said polynucleotide. With respect to claims 5 and 6, Hillman (page 27) teaches a labeling the polynucleotide with a detectable moiety, such as a radiolabel, fluorescent label, chemiluminescent label or chromogenic agent. With reference to claims 50 and 51, Hillman (pages 29 and 36-37) teaches polynucleotide solutions to be used for pharmaceutical purposes. which solutions are considered to include a pharmaceutically-acceptable carrier since the solutions are used for pharmaceutical purposes.

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Query Match 66.9%; Score 1257; DB 3; Length 1440;
Best Local Similarity 99.1%; Pred. No. 0;
Matches 1274; Conservative 0; Mismatches 10; Indels 1; Gaps 1;
Qy 19
CTCCAGCCCGCCCAGTGGCCGCAGTCACCCAGGTCCAGAGGCGGCGGTATCACAGGCTCT
78
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 136
CTCCAGCCCGCCCAGTGGCCGCAGTCACCCAGGTCCAGAGGCGGCGGTATCACAGGCTCT
195
Qy 79
CCGACATGTCTATGCTGGCTGAACGTCGGCGGAAGCAGAAGTGGGCTGTGGATCCTCAGA
138
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 196
CCGACATGTCTATGCTGGCTGAACGTCGGCGGAAGCAGAAGTGGGCTGTGGATCCTCAGA
255
Qy 139
ACACTGCCTGGAGTAATGACGATTCCAAGTTTGGCCAGCGGATGCTAGAGAAGATGGGGT
198
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Db 256
ACACTGCCTGGAGTAATGACGATTCCAAGTTTGGCCAGCGGATGCTAGAGAAGATGGGGT
315
Qy 199
GGTCTAAAGGAAAGGGTTTAGGGGCTCAGGAGCAAGGAGCCACAGATCATATTAAAGTTC
258
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 316
GGTCTAAAGGAAAGGGTTTAGGGGCTCAGGAGCAAGGAGCCACAGATCATATTAAAGTTC
375
Qy 259
AAGTGAAAAATAACCACCTGGGACTCGGAGCTACCATCAATAATGAAGACAACTGGATTG
318
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 376
AAGTGAAAAATAACCACCTGGGACTCGGAGCTACCATCAATAATGAAGACAACTGGATTG
435
Qy 319
CCCATCAGGATGATTTTAACCAGCTTCTGGCCGAACTGAACACTTGCCATGGGCAGGAAA
378
||||||||||||||||||||||||||| ||||||||||||||||||||||||||||||
Db 436
CCCATCAGGATGATTTTAACCAGCTTCTAGCCGAACTGAACACTTGCCATGGGCAGGAAA
495
Qy 379
CCACAGATTCCTCGGACAAGAAGGAAAAGAAATCTTTTAGCCTTGAGGAAAAGTCCAAAA
438
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 496
CCACAGATTCCTCGGACAAGAAGGAAAAGAAATCTTTTAGCCTTGAGGAAAAGTCCAAAA
555
Qy 439
TCTCCAAAAACCGTGTTCACTATATGAAATTCACAAAAGGGAAGGATCTGTCATCTCGGA
498
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 556
TCTCCAAAAACCGTGTTCACTATATGAAATTCACAAAAGGGAAGGATCTGTCATCTCGGA
615
Qy 499
GCAAAACAGATCTTGACTGCATTTTTGGGAAAAGACAGAGTAAGAAGACTCCCGAGGGCG
558
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Db 616
GCAAAACAGATCTTGACTGCATTTTTGGGAAAAGACAGAGTAAGAAGACTCCCGAGGGCG
675
Qy 559
ATGCCAGTCCCTCCACTCCAGAGGAGAACGAAACCACGACAACCAGCGCCTTCACCATCC
618
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 676
ATGCCAGTCCCTCCACTCCAGAGGAGAACGAAACCACGACAACCAGCGCCTTCACCATCC
735
Qy 619
AGGAGTACTTTGCCAAGCCGGTGGCAGCACTGAAGAACAAGCCCCAGGTTCCAGTTCCAG
678
|||||||||||||||||| | ||||||||||||||||||||||||||||||||||||
Db 736
AGGAGTACTTTGCCAAGCGGATGGCAGCACTGAAGAACAAGCCCCAGGTTCCAGTTCCAG
795
Qy 679
GGTCTGACATTTCTGAGACGCAGGTGGAACGTAAAAGGGGGAAGAAAAGAAATAAAGAGG
738
ik||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 796
GGTCTGACATTTCTGAGACGCAGGTGGAACGTAAAAGGGGGAAGAAAAGAAATAAAGAGG
855
Qy 739
CCACAGGTAAAGATGTGGAAAGTTACCTCCAGCCTAAGGCCAAGAGGCACACGGAGGGAA
798
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 856
CCACAGGTAAAGATGTGGAAAGTTACCTCCAGCCTAAGGCCAAGAGGCACACGGAGGGAA
915
Qy 799
AGCCCGAGAGGGCCGAGGCCCAGGAGCGAGTGGCCAAGAAGAAGTGCGCGCCAGCAGAAA
858
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Db 916
AGCCCGAGAGGGCCGAGGCCCAGGAGCGAGTGGCCAAGAAGAAGAGCGCGCCAGCAGAAG
975
Qy 859
AACAGCTCAGAGGCCCCTGCTGGGACCAGAGTTCCAAGGCCTCTGCTCAGGATGCAGGGG
918
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Db 976
AGCAGCTCAGAGGCCCCTGCTGGGACCAGAGTTCCAAGGCCTCTGCTCAGGATGCAGGGG
1035
Qy 919
ACCATGTGCAGCCGCCTGAGGGCCGGGACTTCACCCTGAAGCCCAAAAAGAGGAGAGGGA
978
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 1036
ACCATGTGCAGCCGCCTGAGGGCCGGGACTTCACCCTGAAGCCCAAAAAGAGGAGAGGGA
1095
Qy 979
AGAAAAAGCTGCAAAAACCAGTAGAGATAGCAGAGGACGCTACACTAGAAGAAACGCTAG
1038
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 1096
AGAAAAAGCTGCAAAAACCAGTAGAGATAGCAGAGGACGCTACACTAGAAGAAACGCTAG
1155
Qy 1039 TGA-
AAAAGAAGAAGAAGAAAGATTCCAAATGAATCCTTCCCAGCCGGGGCCTTCCGACC 1097
||| ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 1156
TGANAAAAGAAGAAGAAGAAAGATTCCAAATGAATCCTTCCCAGCCGGGGCCTTCCGACC
1215
Qy 1098
ACTCAGCTGTCAGGGCACTGCGGGGGCAGACACCTCTGGCCTGAAGTCACAGCAGAGTTC
1157
||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 1216
ACTCAGCTGTCAGGGCACTGCGGGGGCAGACACCTCTGGCCTGAAGTCACAGCAGAGTTC
1275
Qy 1158
ACCCCAGAGCGCCTGGGCGCATCTTGTGGCATGCCCATGGGCTGCCGAGTCCTGCCCTCT
1217
|||||||||||| ||||||||||||||||||||||||||||||||||||||||||||||
Db 1276
ACCCCAGAGCGTCTGGGCGCATCTTGTGGCATGCCCATGGGCTGCCGAGTCCTGCCCTCT
1335
Qy 1218
CGCCACATTTCCCCCAAGTTACATTCCCAGGAGGACCTTTTTAATGTTCTCAATCGTGGC
1277
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Db 1336
CGCCACATTTCCCCCAAGTTACATTCCCAGGAGGACCTTTTTAATGTTCTCAATCGTGGC
1395
Qy 1278 TCTCAGACACAAATAAATTCTCGTG 1302
|||||||||||||||||||| | ||
Db 1396 TCTCAGACACAAATAAATTTTTTTG 1420
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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Liao (GenBank Accession No. AF205718) in view of Hillman.

The teachings of Liao are presented above. Liao does not teach labeling the polynucleotide.

However, Hillman (page 27) teaches labeling polynucleotides with a detectable

moiety, such as a radiolabel, fluorescent label, chemiluminescent label or chromogenic agent. Hillman teaches that detectably labeled polynucleotides can be used as probes in hybridization assays to facilitate the detection of complementary target sequences.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have labeled the polynucleotides of Liao with a detectable label in order to accomplish the objective set forth by Hillman of providing labeled polynucleotides that could be used as probes to facilitate the detection of complementary target sequences.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
July 5, 2006

CARLA J. MYERS
PRIMARY EXAMINER